UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SHAUN L.W. SAMUELS,

Plaintiff,

v.

TRIVASCULAR CORPORATION, et al.,

Defendants.

Case No. 13-cv-02261-EMC

CLAIM CONSTRUCTION ORDER

Docket Nos. 81-82, 84

Plaintiff Shaun L.W. Samuels is the owner of the '575 patent which concerns an inflatable stent. Dr. Samuels has accused Defendant TriVascular Corporation and several individuals affiliated with the company of patent infringement (collectively, "TriVascular"). Currently pending before the Court are the parties' competing briefs regarding claim construction of the '575 patent.

I. FACTUAL & PROCEDURAL BACKGROUND

As noted above, the '575 patent concerns an inflatable stent. For the most part, a representative claim from the patent is claim 1. Claim 1 reads as follows:

> 1. An inflatable intraluminal stent adapted to be secured to the interior of a tubular structure within the human body comprising:
>
> a) **an inflatable and deflatable cuff of generally hollow cylindrical continuation** having a collapsible lumen, an inner surface, an inlet, an outlet and a friction enhancing outer surface, said friction-enhancing outer surface featuring **inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff**, **said friction-enhancing outer surface engaging the interior of the tubular structure without penetration to prevent the cuff from moving** in a longitudinal direction with respect to the tubular structure wen said cuff is in a fully inflated condition;

> b) **means for injecting an inflation material into said cuff to inflate it**; and
>
> c) **a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation**.

'575 patent, claim 1 (emphasis added). Terms to be construed include those bolded above.

II. DISCUSSION

A. Legal Standard

Claim construction is a question of law to be determined by the Court. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) ("hold[ing] that in a case tried to a jury, the court has the power and obligation to construe as a matter of law the meaning of language used in the patent claim"). "The purpose of claim construction is to 'determin[e] the meaning and scope of the patent claims asserted to be infringed.'" *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008).

> Words of a claim are generally given their ordinary and customary meaning, which is the meaning a term would have to a person of ordinary skill in the art after reviewing the intrinsic record at the time of the invention. "In some cases, the ordinary meaning of claim language . . . may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." However, in many cases, the meaning of a claim term as understood by persons of skill in the art is not readily apparent.

Id.

> Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." Those sources include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art."

Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005). As a general matter, extrinsic evidence such as dictionaries and expert testimony is considered less reliable than intrinsic evidence (*i.e.*, the patent and its prosecution history). *See id.* at 1317-19 (noting that "extrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent

claim scope unless considered in the context of the intrinsic evidence").

Generally, embodiments from the specification should not be imported into the claims as limitations. *See Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1369 (Fed. Cir. 2012) ("We do not read limitations from the specification into claims."). "There are only two exceptions to this general rule: (1) when a patentee sets out a definition and acts as his own lexicographer, or (2) when the patentee disavows the full scope of the claim term either in the specification or during prosecution." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012).

B. "means for injecting an inflation material into said cuff to inflate it" *and* "means for inflating the cuff with inflation material"

Dr. Samuels's Proposed Construction	**TriVascular's Proposed Construction**	**Court's Construction**
"means for injecting an inflation material into said cuff to inflate it"		
Function: The function is injecting an inflation material into said cuff to inflate it. **Structure:** The corresponding structure is an inflation device, such as the kind of syringe shown in Figs. 1 and 9a-9c (71, 117) and inflation tubing (61, 115).	**Function:** The same. **Structure:** The corresponding structure is an inflation syringe of the kind shown in Figs. 1 and 9a-9c (71, 117) containing an inflation material; inflation tubing (61, 115) with a mating end (63) that opens a valve by separating opposing leaflets (51, 53) that are in an inflation port (39, 123) to inflate the cuff.	**Function:** The function is injecting an inflation material into said cuff to inflate it. **Structure:** The corresponding structure is an inflation syringe of the kind shown in Figs. 1 and 9a-9c (71, 117), inflation tubing (61, 115), and a valve.

"means for inflating the cuff with inflation material"		
Function: The function is inflating the cuff with inflation material. **Structure:** The corresponding structure is an inflation device, such as the kind of syringe shown in Figs. 1 and 9a-9c (71, 117) and inflation tubing (61, 115).	**Function:** The same. **Structure:** The corresponding structure is an inflation syringe of the kind shown in Figs. 1 and 9a-9c (71, 117) containing an inflation material; inflation tubing (61, 115) with a mating end (63) that opens a valve by separating opposing leaflets (51, 53) that are in an inflation port (39, 123) to inflate the cuff with the inflation material.	**Function:** The function is inflating the cuff with inflation material. **Structure:** The corresponding structure is an inflation syringe of the kind shown in Figs. 1 and 9a-9c (71, 117), inflation tubing (61, 115), and a valve.

The first term ("means for injecting an inflation material into said cuff to inflate it") can be found in, *e.g.*, claim 1(b). The second term ("means for inflating the cuff with inflation material") can be found in, *e.g.*, claim in 14(c).

Both parties agree that the two terms should be considered together. Both parties also agree that the above terms are means-plus-function limitations. Means-plus-function limitations were, at the time, governed by paragraph 6 of 35 U.S.C. § 112, which provided as follows:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. § 112 (1999).

> In enacting this provision, Congress struck a balance in allowing patentees to express a claim limitation by reciting a function to be performed rather than by reciting structure for performing that function, while placing specific constraints on how such a limitation is to be construed, namely, by restricting the scope of coverage to only the structure, materials, or acts described in the specification as corresponding to the claimed function and equivalents thereof.

Williamson v. Citrix Online, LLC, 792 F.3d 1339, 1347 (Fed. Cir. 2015) (en banc).

Here, the parties do not have a dispute as to what the claimed functions of the means-plus-function elements are – *i.e.*, injecting an inflation material into the cuff to inflate it and inflating the cuff with inflation material. (As indicated by the above, the functions for the two elements are essentially the same.) Rather, the parties dispute what the corresponding structure for each function is. Dr. Samuels argues that, in each case, the structure that performs the function is simply a syringe and inflation tubing. In response, TriVascular contends that the structure is not just a syringe and inflation tubing but also includes a valve.[1]

In his papers, Dr. Samuels contends that a valve should not be part of the structure because there is a *different* claim element (*e.g.*, claim 1(c) instead of claim 1(b)) that addresses a valve. *See* Op. Br. at 9. But as TriVascular argues in its papers, one structure can perform multiple functions, not just one – *i.e.*, nothing bars a valve from performing the function of "permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation" (claim 1(c)) and *also* performing the function of inflating the cuff with inflation material (claim 1(b)). This makes practical sense. In addition, TriVascular has support for its position from *Intellectual Property Development, Inc. v. UA-Columbia Cablevision of Westchester, Inc.*, 336 F.3d 1308 (Fed. Cir. 2003) (hereinafter *IPD*).

In *IPD*, one element in the claim at issue was "'*light beam demodulation means* at said reception position responsive to said *photo-sensitive detector means* to convert said light beam

[1] TriVascular's construction also refers to, *e.g.*, the mating end of inflation tubing, leaflets, an inflation port, and inflation material, *see* Resp. Br. at 5, but at the core of its argument is the valve.

into demodulated high frequency carrier radio wave signals modulated with video broadcast signals.'" *Id.* at 1312 (emphasis added). According to the district court,

> since the claim language requires that the "photo-sensitive detector means" and the "light beam demodulation means" be "responsive to" each other, they could not, as urged by [the plaintiff], be contained in the same structure, i.e., the photo-sensitive detector. Otherwise, according to the court, the words 'responsive to' would be read out of the claim.

Id. at 1318. The Federal Circuit disagreed with the district court, stating as follows: "Contrary to [the defendant's] argument, we see no reason why, as a matter of law, one claim limitation may not be responsive to another merely because they are located in the same physical structure." *Id.* at 1320 n.9. At least one court has expressly cited *IPD* for the proposition that "multiple claimed functions can share the same corresponding structure or structures." *Morvil Tech. v. Medtronic Ablation Frontiers*, No. 10-CV-2088 BEN (BGS), 2012 U.S. Dist. LEXIS 113029, at *51 (S.D. Cal. Aug. 10, 2012).

The instant case, of course, is somewhat different from *IPD*. In *IPD*, the Federal Circuit was confronted with *two* means-plus-function elements (the light beam demodulation means and the photo-sensitive detector means), and that is not the case here. But the underlying point of *IPD* still has application in the case at bar – *i.e.*, a valve is not automatically foreclosed from being structure for purposes of claim 1(b) just because it also shows up in claim 1(c).

Dr. Samuels protests, however, that just because a valve is part of the inflating process does not mean that the valve does the inflating itself; what does the actual inflating is the syringe and inflation tubing. Admittedly, Dr. Samuels has some support for his position from the '575 specification, which states, *inter alia*, as follows: "Referring back to FIG. **1**, cuff **17** is inflated by way of an inflation syringe **71** with an inflation material **73**." '575 patent, col. 4:33-34.

But, notably, other parts of the '575 specification indicate that a valve is not just a part of the inflation process; rather, it is a *necessary element* to accomplish the inflation. *Compare Welker Bearing Co. v. PHD, Inc.*, 550 F.3d 1090, 1097 (Fed. Cir. 2008) (emphasis added) (noting that a "'court may not import . . . structural limitations from the written description that are *unnecessary* to perform the claimed function'") (emphasis added); *see also Wenger Mfg., Inc. v.*

Coating Machinery Sys., Inc., 239 F.3d 1225, 1233 (Fed. Cir. 2001) (stating that "the court improperly restricted 'air circulation means' limitation to structure that was disclosed in the preferred embodiment, but was not necessary to perform the recited function of circulating air").

- "The cuff **17** is inflated and deflated *by means of a valve*, indicated generally at **37** in FIGS. **4***a* and **4***b*, which is integral with inflation port **39** of cuff **17**." '575 patent, col. 4:8-10 (emphasis added).
- "As shown in FIG. **4***a*, when inflation tubing **61** is in an engaged configuration *with valve* **37**, mating end **63** separates opposing leaflets **51** and **53** so that cuff **17** may be inflated or deflated." '575 patent, col. 4:17-20 (emphasis added).

That a valve is a necessary element to accomplish inflation is underscored by the fact that the inflation material can be "a saline-based fluid or a material that contains a photo-activated or heat-activated hardening agent or any hardening agent that hardens over time." '575 patent, col. 4:35-37. In either case, the valve is necessary to accomplish inflation (and not just prevent deflation after inflation is achieved, *see* Part II.D, *infra*) or the material will, in effect "leak out." This is true even where the material contains a hardening agent because hardening is a process that takes at least some time.

In response, Dr. Samuels suggests that a valve is not necessary based on the language of claims 9 and 19. Claim 9 covers "[t]he inflatable intraluminal stent of claim **1** wherein the valve is of a breakaway design to permit separation *from the means for injecting*." '575 patent, claim 9 (emphasis added). Claim 19 covers "[t]he apparatus of claim **14** wherein the valve is of a breakaway design to permit separation *from the means for inflating*." '575 patent, claim 19 (emphasis added); *see also* '575 patent, claim 13 (addressing "[t]he inflatable intraluminal stent of claim **1** wherein the means for injecting an inflation material into said inflatable cuff to inflate it includes an inflation syringe and inflation tubing"). But TriVascular correctly notes that the Federal Circuit has "long held that a patentee cannot rely on claim differentiation to broaden a means-plus-function limitation beyond those structures specifically disclosed in the specification." *Saffran v. Johnson & Johnson*, 712 F.3d 549, 563 (Fed. Cir. 2013); *see also Nomos Corp. v. BrainLAB USA, Inc.*, 357 F.3d 1364, 1368 (Fed. Cir. 2004) (noting that "our interpretation of the

corresponding structure comes from the written description, not from [a] dependent claim"; adding that "claim differentiation, which is a 'guide, not a rigid rule,' does not override the requirements of § 112, ¶ 6 when the 'claim will bear only one interpretation'"; and thus concluding that the means for "generating at least one ultrasound image" includes both an ultrasound probe and a fixation device, not just the probe alone).

Accordingly, the corresponding structure for the two means-plus-function limitations identified above is an inflation syringe of the kind shown in Figs. 1 and 9a-9c (71, 117), inflation tubing (61, 115), *and* a valve. Section 112 ¶ 6, of course, also provides coverage for equivalents thereof.

C. "inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff"

Dr. Samuels's Proposed Construction	**TriVascular's Proposed Construction**	**Court's Construction**
A portion or portions of the outer surface of the cuff that protrude outward of the cuff upon inflation.	A portion or portions of the outer surface of the inflatable cuff that are themselves inflatable by being filled with fluid that protrude outward from the flat portions of the outer surface of the inflated cuff, including at least one ridge that goes around the cuff.	A portion or portions of the outer surface of the inflatable cuff that protrude outward of the cuff and that are themselves inflatable, *i.e.*, expandable by being filled with fluid, including at least one ridge that goes around the cuff.

The term can be found in, *e.g.*, claim 1(a).

As argued by TriVascular, the main dispute regarding the term seems to be whether the protrusions, which are themselves inflatable, must be inflatable by being filled with fluid. In his

reply brief, Dr. Samuels failed to address this point. *See* Reply at 6. That being the case, the Court adopts the limitation advocated for by TriVascular (*i.e.*, as unopposed).

Moreover, there is a substantive basis supporting the "fluid" limitation. Although the bulk of the '575 patent, including the specification, does not make any mention of the protrusions being filled with fluid, the specification does state: "As illustrated in FIG. **2**, circumferential ridges **25** are in fluid communication with the inflatable chamber **27** of cuff **17**." '575 patent, col. 3:54-56. *Cf. ICU Med., Inc. v. Alaris Med. Sys.*, 558 F.3d 1368, 1374-75 (Fed. Cir. 2009) (agreeing with district court's construction of "spike" to mean "'an elongated structure having a pointed tip for piercing the seal, which tip may be sharp or slightly rounded'" because it is "appropriate 'to rely heavily on the written description for guidance as to the meaning of the claims'" and "the specification 'repeatedly and uniformly describes the spike as appointed instrument for the purpose of piercing a seal inside the valve'").[2]

Furthermore, as TriVascular argues, the "fluid" limitation is supported based on what Dr. Samuels told the PTAB during the inter partes review ("IPR") proceedings. In this regard, TriVascular makes a prosecution disclaimer-type argument. That doctrine "'preclud[es] patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution.'" *TomTom, Inc. v. Adolph*, 790 F.3d 1315, 1325 (Fed. Cir. 2015). While the doctrine does not apply

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[2] Notably, the *ICU* court acknowledged that "we should not import limitations from the specification ino the claims." *ICU*, 558 F.3d at 1375. The court added, however, that

> "the line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court's focus remains on understanding how a person of ordinary skill in the art would understand the claim terms." Indeed, the court should focus on how such a person would understand the claim term "after reading the entire patent." *The specification never suggests that the spike can be anything other than pointed.* As the district court noted, (1) each figure depicts the spike as elongated and pointed; (2) in each figure depicting an activated valve, the spike pierces the seal; and (3) the patents neither describe piercing as optional nor describe any non-piercing item as a spike. Moreover, ICU offers no support from any intrinsic or extrinsic source in support of its claim that the ordinary meaning of spike would include a non-pointed structure such as a tube or a straw.

Id. (emphasis added).

"'where the alleged disavowal of claim scope is ambiguous,'" it "'attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender'" where "'the patentee has unequivocally disavowed a certain meaning to obtain his patent.'"[3] *Id.*

Before the PTAB, Dr. Samuels argued that the protrusions must be inflatable and that they "are unarguably identified by the circumferential ridges, such as ridges 25 in one embodiment clearly shown in Figure 2 . . . and are themselves in fluid communication with the inflatable chamber 27 of cuff 17." Cohen Decl., Ex. 3 (Resp. at 5-6). He also argued that "the only supporting disclosure in the '575 patent is for a ridge which is itself part of the inflatable protrusion and contains fluid itself[;] [t]here simply is no support for the ridge being solid." Cohen Decl., Ex. 3 (Resp. at 7). Ultimately, the PTAB adopted a construction in favor of Dr. Samuels, "determ[ing] that 'inflatable protrusions' are protrusions that are themselves inflatable, i.e., expandable by being filled with fluid," as contended by Dr. Samuels. Cohen Decl., Ex. 4 (PTAB Decision at 7, 10). Thus, based on the record, there is support for TriVascular's argument that prosecution disclaimer is applicable here.

Accordingly, the Court construes the above-identified term as "a portion or portions of the outer surface of the inflatable cuff that protrude outward of the cuff and that are themselves inflatable, *i.e.*, expandable by being filled with fluid, including at least one ridge that goes around the cuff."

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[3] At least two judges in this District have noted that prosecution disclaimer has viability in IPR proceedings, even though an IPR is technically an adjudicative proceeding rather than an examination. *See, e.g.*, *Evolutionary Intelligence, LLC v. Sprint Nextel Corp.*, No. C013094513, 2014 U.S. Dist. LEXIS 139066, at *20 (N.D. Cal. Sept. 26, 2014) (Whyte, J.) ("The IPR proceedings will also add to the '536 Patent's prosecution history. Prosecution history is an important part of the intrinsic record relevant to claim construction. Statements made by Evolutionary Intelligence during the IPR could disclaim claim scope, aid the court in understanding the meaning of the terms, or otherwise affect the interpretation of key terms."); *Pragmatus AV, LLC v. Yahoo! Inc.*, No. C-13-1176 EMC, 2014 U.S. Dist. LEXIS 65813, at *14-15 (N.D. Cal. May 13, 2014) ("Under Federal Circuit law, comments made by a patent holder during inter partes reexamination proceedings can limit claim scope. The same should be true now that inter partes review, rather than inter partes reexamination, is in effect."). And even if prosecution disclaimer is not an exact fit because an IPR is an adjudicative proceeding, it is analogous to judicial estoppel. *See Abbott Labs. v. Church & Dwight Co.*, No. 07 C 3428, 2008 U.S. Dist. LEXIS 103635, at *25 (N.D. Ill. Dec. 22, 2008) ("not[ing] that the doctrine of prosecution disclaimer is arguably analogous to the concept of judicial estoppel, which applies only if the party to be estopped was successful in the prior proceeding").

D. "a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation"

Dr. Samuels's Proposed Construction	**TriVascular's Proposed Construction**	**Court's Construction**
"a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation"		
Any structure that affects fluid flow, formed or combined as a unit with the cuff, and is capable of not stopping inflation material from entering the cuff from the means for injecting and capable of stopping inflation material from leaving the cuff after the injection material has entered the cuff to prevent deflation.	A device built-in to the [cuff, inflation port, or one of the cuffs] that has a movable part (such as leaflets) that open to permit entry of the inflation material and thereafter closes to seal the cuff to prevent deflation. This construction does not cover inflation tubing inserted into an inflation port with an interference fit.	A valve, integral with the inflatable cuff, that has a movable part or parts (such as leaflets) that open to permit entry of the inflation material and thereafter close to seal the cuff to prevent deflation.
"a valve"		
Any structure that affects fluid flow.	A device built-in to the [cuff, inflation port, or one of the cuffs] that has a movable part (such as leaflets) that open to permit entry of the inflation material and thereafter closes to seal the cuff to prevent deflation. This construction	See above.

	does not cover inflation tubing inserted into an inflation port with an interference fit.	
"for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation"		
Capable of not stopping inflation material from entering the cuff from the means for injecting and capable of stopping inflation material from leaving the cuff after the injection material has entered to cuff to prevent deflation.	A device built-in to the [cuff, inflation port, or one of the cuffs] that has a movable part (such as leaflets) that open to permit entry of the inflation material and thereafter closes to seal the cuff to prevent deflation. This construction does not cover inflation tubing inserted into an inflation port with an interference fit.	See above.

The terms can be found in, *e.g.*, claim 1(c).

As a preliminary matter, the Court takes note that, according to TriVascular, the phrase "a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation" (*see, e.g.*, claim 1(c)) should be construed in its entirety. While Dr. Samuels has provided a construction for the entirety of the phrase, he also asserts that the Court should really just construe parts of that phase separately, namely (1) "a valve" and (2) "for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation." *See* Op. Br. at 16 (arguing that "Trivascular has impermissibly combined several terms and characterized them as one term"). The Court agrees with TriVascular that it makes more sense to construe the phrase in its entirety rather than in isolated portions, especially given the particular disputes between the parties

regarding the terms in the context of the entire phrase.

In evaluating the phrase "a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation," the Court begins by noting that there is some ambiguity. More specifically, is the valve at issue one that (1) permits entry of the inflation material and that (2) *actually* seals the cuff itself?[4] Or is the valve at issue one that (1) permits entry of the inflation material and that (2) *permits* sealing of the cuff (but does not do the actual sealing itself)?[5] The grammatical structure of the claim language better supports the first interpretation – *i.e.*, the valve permits entry and actually seals the cuff itself. Notably, there is parallel construction between the words "permitting" and "sealing." *Compare* '851 patent, claim 6(b)[6] (claiming "[a]n apparatus for affixing an endoluminal device to the walls of tubular structures with in the body comprising [*inter alia*] a valve integral with said cuff to permit inflation and deflation"). Moreover, at the claim construction hearing, Dr. Samuels never argued in favor of the second interpretation; instead, he agreed that claim 1(c) requires that the valve both permit entry and do the sealing itself.

With this understanding, the main question becomes whether a valve that permits entry and thereafter seals is a valve that (1) has moveable parts that open and close, such as a mitre valve (TriVascular's position), or that (2) can be such a valve but that can also be a valve without movable parts, such as a breakaway valve (Dr. Samuels's position). The Court concludes that Dr. Samuels's position is not persuasive.

First, it is notable that the phrase states the valve permits entry and "*thereafter* seal[s] . . . to prevent deflation." '575 patent, claim 1(c) (emphasis added). The use of the word "thereafter" is important. It indicates that, *after* inflation, the valve seals to prevent deflation. A breakaway valve may seal and prevent deflation *during* the inflation process (*i.e.*, while the inflation tubing is

[4] In other words, does the word "permitting" modify only the word "entry" and not the word "sealing"?

[5] In other words, does the word "permitting" modify both the word "entry" and the word "sealing"?

[6] The '851 patent is another patent owned by Dr. Samuels.

inserted), as Dr. Samuels argued at the hearing, but during and after are not the same thing. With a breakaway valve, after inflation, the inflation tubing is removed, *see* '575 patent, col. 4:24-27 (stating that, "[r]eferring to FIG. **4***b*, once cuff **17** has been inflated (or deflated) to the desired level, a sharp tug on inflating tubing **61** in a direction away from inflation port **39** causes circumferential notch **65** [part of the inflation tubing] and circumferential rim **55** [part of the breakaway valve] to disengage"), and there is nothing in the '575 patent to indicate that the breakaway valve itself seals, as opposed to, *e.g.*, a hardening agent in the inflation material. *See* '575 patent, col. 4:34-43 ("The inflation material could be a saline-based fluid or a material that contains a photo-activated or heat-activated hardening agent or any hardening agent that hardens over time. . . . After cuff **17** has been installed and inflated, the material **73** hardens over time to permanently affix stent **5** within the tubular structure of the body via circumferential ridges.").

Second, although it is possible for the inflation material to seal itself allowing the breakaway valve to be removed, the '575 specification clearly contemplates that the inflation material can be a fluid *without* any hardening agent. *See* '575 patent, col. 4:34-37 ("The inflation material could be a *saline-based fluid or* a material that contains a photo-activated or heat-activated hardening agent or any hardening agent that hardens over time.") (emphasis added). That being the case, claim 1 of the '575 patent requires a valve that permits entry and thereafter seals either with *or* without the use of any hardening agent in the inflation material. Indeed, this is underscored by dependent claim 7 which requires inflation material *with* a hardening agent. *See* '575 patent, claim 7 (covering "[t]he inflatable intraluminal stent of claim 1 wherein the inflation material includes a hardening agent"). Dr. Samuels has failed to explain how a breakaway valve could do the sealing (after inflation is completed) in a case where the fluid (inflation material) does not contain any hardening agent without, *e.g.*, a mitre valve. While, at the hearing, Dr. Samuels asserted that there could be some other kind of valve without movable parts that could do sealing, even without any hardening agent – *e.g.*, if the valve had a physical structure with a decreasing orifice size, such that, with the right pressure, inflation material could be forced in but would not thereafter "leak out" – he failed to offer any evidence showing that this was in fact possible. Furthermore, nothing in the patent specifications suggests such a valve. *See* note 2,

supra.

Third, as TriVascular points out, in multiple places in the specification, there are only references to a valve that seals being a valve that closes (such as a mitre valve) – which would require movable parts associated with the valve. *See, e.g.*, '575 patent, col. 4:29-32 (stating that, "[u]pon withdrawal of the mating end **63** of inflation tubing **61**, . . . opposing leaflets **51** and **53** of mitre valve **45** close to seal the inflated cuff **17**"); '575 patent, col. 6:26-29 (stating that, "[a]s the catheter is pulled away, the breakaway valve within port **123** releases inflation tubing **115** and the mitre valve [which has leaflets that open and close] seals port **123** in a manner similar to the one illustrated in FIG. **4***b*"); *see also* note 2, *supra*. This is consistent with the position that Dr. Samuels took before the PTAB in the IPR proceeding. *See, e.g.*, Cohen Decl., Ex. 1 (Prelim. Resp. at 2) (stating that "[s]tent 5 also includes a means for injecting or inflating with an inflation material and a valve 45 [*i.e.*, a mitre valve[7]] for permitting entry of the inflation material into cuff 17 and thereafter sealing cuff 17 to prevent deflation"); Cohen Decl., Ex. 3 (Resp. at 4) (stating that "[s]tent 5 also includes a valve 45 [*i.e.*, a mitre valve] for permitting entry of the inflation material into cuff 17, allowing deflation, and finally sealing cuff 17 to prevent deflation").

Finally, dependent claims 8 and 9 are not sufficient to establish that a valve that seals after inflation can be one without movable parts. For example, claim 8 covers "[t]he inflatable intraluminal stent of claim **1** wherein the valve is a mitre valve." '575 patent, claim 8. But simply because a mitre valve is called out in claim 8 does not thereby mean that a breakaway valve (or other valve without movable parts) is a valve that seals thereafter, as required in claim 1. A mitre valve is one specific kind of valve with movable parts; Dr. Samuels has not demonstrated that there are not others. *See also Phillips*, 415 F.3d at 1315 (noting that "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim"). Claim 9 covers "[t]he inflatable intraluminal stent of claim **1** wherein the valve is of a breakaway design to permit separation from the means for injecting." '575 patent, claim 9. But claim 9 need not be interpreted to mean that a breakaway valve is

[7] *See* '575 patent, col. 4:12-14 (stating that "[m]itre valve **45** features opposing leaflets **51** and **53** which are constructed of a non-elastomeric, biologically inert material").

therefore a valve that seals after inflation, as required by claim 1. It does not preclude a breakaway valve in addition to, *e.g.*, a mitre valve as shown in the drawings. In other words, claim 9 can be interpreted to mean that the valve that actually seals in claim 1 (such as a mitre valve) is given an additional feature – *i.e.*, a breakaway design. In fact, that interpretation makes more sense given the language in claim 9 that the breakaway design's purpose is "to permit separation from the means for injecting," and therefore not to seal.

Accordingly, the Court construes the phrase "a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation" as follows: "a valve, integral with the inflatable cuff, that has a movable part or parts (such as leaflets) that open to permit entry of the inflation material and thereafter close to seal the cuff to prevent deflation." The Court need not add limitations beyond that, as suggested by TriVascular, as a valve involving inflation tubing inserted into an inflation port with an interference fit does not have a movable part or parts. Likewise, the Court need not add language regarding capability, as proposed by Dr. Samuels, because it is confusing and unnecessary given the construction above.

E. "inflatable and deflatable cuff of generally hollow cylindrical continuation [sic configuration]"[8]

Dr. Samuels's Proposed Construction	**TriVascular's Proposed Construction**	**Court's Construction**
Cuff of generally hollow configuration.	A band-like structure that has an inner surface and outer surface creating an inflatable chamber that may be inflated by filling the chamber with fluid or deflated by allowing	A cuff, of generally hollow configuration, that has an inner surface and an outer surface and an inflatable and deflatable chamber in between the surfaces.

[8] The Court **GRANTS** TriVascular's administrative motion to file notice of supplemental citation. *See* Docket No. 90.

	the fluid to leave in ordinary use.	

This term can be found in, *e.g.*, claim 1(a).

As a preliminary matter, the Court takes note that Dr. Samuels has asked for construction of a slightly narrower term – *i.e.*, "cuff of generally hollow cylindrical continuation [sic configuration]." However, it is proper to construe the broader term, as advocated by TriVascular, particularly given Dr. Samuel's objection to TriVascular's proffered construction. *See, e.g.*, Reply at 12 (arguing that "[t]here is no support for adding the additional language of an inflatable chamber, nor is it needed").

The crux of the dispute here (which was not fully fleshed out until the hearing) is whether a cuff has an inflatable chamber between the cuff's inner surface and outer surface. *See, e.g.*, '575 patent, Fig. 2 (inflatable chamber at **27**); '575 patent, col. 3:54-56 ("As illustrated in FIG. **2**, circumferential ridges **25** are in fluid communication with the inflatable chamber **27** of cuff **17**."). TriVascular argues that a cuff does; Dr. Samuels argues that a cuff can have an inflatable chamber but such is not required; that is, it is permissible to have only the inflatable protrusion(s) inflated.

Dr. Samuels's position is without merit. The cuff is expressly described as "inflatable and deflatable" in the term. To be inflatable, there must be a chamber within the cuff that can be filled with inflation material. If the '575 patent was intended to cover only an expandable cuff, then Dr. Samuels could easily have used the term "expandable" or a word akin thereto. Instead, he chose the word "inflatable," a word that is also used in the patent term "inflatable protrusions." Dr. Samuels has failed to explain why "inflatable" should have one meaning when used in conjunction with the cuff and a different meaning when used in conjunction with the protrusions.[9]

[9] In a supplemental brief, Dr. Samuels argued that "inflatable cuff" may still refer to a cuff with only the inflatable protrusion(s) inflated because the inflatable protrusion(s) is/are *part* of the cuff. *See* Docket No. 91 (Dr. Samuels's Supp. Br. at 2) (arguing that "the inflatable cuff of claim 1 may be inflated by inflation of just the inflatable protrusion(s) which is/are part of the 'cuff' as claimed"). But this argument is not persuasive because the cuff is the entire structure; thus, an "inflatable cuff" must mean that the entire structure is inflated. Notably, nowhere in the specification is it suggested that an inflatable cuff can be a cuff with only a portion of it inflated. *See* note 2, *supra*. Moreover, given that the claim allows for only one circumferential ridge, Dr.

At the hearing, Dr. Samuels pointed to independent claims 14 and 23 as supportive of his position, *see generally Tandon Corp. v. U.S. Int'l Trade Comm'n*, 831 F.2d 1017, 1023 (Fed. Cir. 1987) (stating that "[t]here is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims" and that, "[t]o the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant"), but the Court is unpersuaded. Admittedly, claim 14 does refer to "a cuff having a collapsible lumen, an inner surface and a friction-enhancing outer surface with an inflatable and deflatable chamber disposed there between." '575 patent, claim 14. But simply because the cuff, as described in claim 14, refers to an inflatable and deflatable chamber, does not mean that the cuff, as described in other claims (*e.g.*, claim 1) does not have such a chamber. "The doctrine of claim differentiation is at its strongest . . . 'where the limitation that is sought be "read into" an independent claim already appears in a dependent claim.'" *InterDigital Communs., LLC v. ITC*, 690 F.3d 1318, 1324 (Fed. Cir. 2012). But here, claims 14 and 23 are not dependent claims; they, like claim 1, are independent claims. Notably, the Federal Circuit has stated that it has

> been cautious in assessing the force of claim differentiation in particular settings, recognizing that patentees often use different language to capture the same invention, discounting it where it is invoked based on independent claims rather than the relation of an independent and dependent claim, and not permitting it to override the strong evidence of meaning supplied by the specification.

Atlas IP, LLC v. Medtronic, Inc., No. 2015-1071, 2015 U.S. App. LEXIS 18819, at *16 (Fed. Cir. Oct. 29, 2015). The Court also notes that "'[a] further reason for not applying the doctrine of claim differentiation in this case is that the [claims at issue] are not otherwise identical." *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1370 (Fed. Cir. 2007) (noting that "there are numerous other differences varying the scope of the claimed subject matter"). Claim 1, for example, is targeted to an "inflatable intraluminal stent" specifically whereas claim 14 is directed more broadly to an "apparatus for disposition within the lumen of a tubular structure."

Samuels's construction makes little sense because, if only that ridge (and not the cuff) is inflated, the cuff would consist of simple ring and not a cylinder.

Accordingly, the Court construes the phrase ""inflatable and deflatable cuff of generally hollow cylindrical continuation [sic configuration]" as "a cuff, of generally hollow configuration, that has an inner surface and an outer surface and an inflatable and deflatable chamber in between the surfaces." The Court declines to provide a specific definition for the term "cuff" (*e.g.*, as a band-like structure) as the term is understandable to a lay person.

F. "affixing the cuff with [sic within] the lumen of the tubular structure without penetration of the tubular structure"

Dr. Samuels's Proposed Construction	**TriVascular's Proposed Construction**	**Court's Construction**
Causing the cuff to resist movement within the lumen of the tubular structure without penetration of the tubular structure.	The cuff is fixedly secured to the interior of the tubular structure to hold it in place without penetration of the tubular structure.	Plain and ordinary meaning.

This term can be found in, *e.g.*, claim 14(b).

The Court sees no need to define the claim term, not only because the word "affixing" is not a term beyond a lay person's comprehension but also because there is no real difference between the parties' proposed constructions. This is substantiated by the specification of the patent which describes "affixing" in the following contexts:

- "If the initial placement of the stent within the tubular structure is not optimal, it may be deflated, repositioned to the optimal position and reinflated so as to again be affixed to the tubular walls via its outer surface." '575 patent, col. 2:39-42.
- "As shown in FIG. **1**, outer surface **23** features a number of inflatable ridges **25** disposed about its circumference. While inflatable ridges are shown in the FIGS., any friction-enhancing outer surface, that would secure the inflated stent to the interior wall of a tubular structure without penetrating it, could be used." '575 patent, col. 3:33-37.

- "As illustrated in FIG. **3**, the outer surface **30** of the cuff is made coarse by a combination of raised portions **31** and lowered portions **33**. These surface features allow the inflated stent to grip the interior walls of a tubular structure with a force that is sufficient to prevent its migration." '575 patent, col. 3:62-66.
- "In addition, it may be desirable in some applications to provide the cuff with an outer surface that promotes tissue ingrowth. This would allow the stent to become more integrated, and thus more firmly affixed, within the tubular structure as time progresses." '575 patent, col. 4:1-5.
- "As shown in FIGS. **5***c* and **6***c*, stent **89** is inflated so that the size of the lumen of stent **89** approximates the lumen size of the original, unconstructed blood vessel. By doing so, constricted portion **83** is compressed between blood vessel wall **85** and stent **89**, the latter of which is fixed in place by way of protruding ridges **91**." '575 patent, col. 4:59-64.
- "A unique feature of the present invention is its capability of being optimally positioned within a tubular structure in the body (in this case, a blood vessel) without causing damage to the surrounding tissue. Specifically, after stent **89** has been inflated so that ridges **91** affix the stent to the tubular walls without penetration, the position of the stent is examined fluoroscopically to determine if it is optimal. If not, stent **89** may be deflated, repositioned and then reinflated." '575 patent, col. 4:66-5:7.
- "The stent-graft is secured to the vessel walls via ridges **96** so that blood passes through graft **92**." '575 patent, col. 5:32-33.

Dr. Samuels's position, as articulated during the IPR proceedings, does not indicate anything different. *See* Cohen Decl., Ex. 11 (Clark Decl. ¶¶ 5(a), 8) (referring to the ridges "holding the stent in place" and "maintain[ing] a desired position"); Cohen Decl., Ex. 12 (Samuels Decl. ¶ 4(b)) (noting that the stent can be "held fixed in a desired location").

Moreover, claim 14(b) itself reads in full as follows: "said friction-enhancing outer surface featuring inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff and affixing the cuff with the lumen of the tubular structure without penetration of the tubular structure when the cuff is fully inflated *so that movement of the cuff in a longitudinal*

direction with respect to the tubular structure is prevented." '575 patent, claim 14(b) (emphasis added). The meaning of "affix" is clear, particularly when viewed in the context of the italicized language. Given the context of the full claim limitation, there is no need to reiterate the point that movement is resisted or that the cuff is held in place.

G. "said friction-enhancing outer surface engaging the interior of the tubular structure without penetration to prevent the cuff from moving"

Dr. Samuels's Proposed Construction	**TriVascular's Proposed Construction**	**Court's Construction**
Outer surface capable of engaging the interior of the tubular structure without penetration and capable of preventing the cuff from moving and enhancing friction.	Said friction enhancing outer surface gripping the interior of the tubular structure with sufficient force to fixedly secure the cuff to keep/hold it in place without penetration of the tubular structure.	Plain and ordinary meaning.

This term can be found in, *e.g.*, claim 1(a).

Basically, the dispute here is similar to the one immediately above, and the Court therefore rests on plain and ordinary meaning.

III. CONCLUSION

For the foregoing reasons, the Court adopts the above constructions for the claim terms at issue.

IT IS SO ORDERED.

Dated: November 12, 2015

EDWARD M. CHEN
United States District Judge